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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/882,126	06/15/2001	Assaf Govari	BIO-136	8637

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EXAMINER

SMITH, FANGEMONIQUE A

ART UNIT PAPER NUMBER

3736

DATE MAILED: 09/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/882,126	Applicant(s) GOVARI, ASSAF	
	Examiner Fangemonique Smith	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 June 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/3/01, 3/13/03</u> . | 6) <input checked="" type="checkbox"/> Other: <u>See Continuation Sheet</u> . |

Continuation of Attachment(s) 6). Other: IDS - 3/24/03, 12/22/03, and 4/20/05.

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

2. Claims 4 and 5 are objected to because of the following informalities:
- a. At lines 2 and 3 of claim 4, the claim recites "an externally applied field at the site within the patient". It is unclear what is being limited by this claim. Appropriate correction is required.
 - b. At line 2 of claim 5, the claim recites " the externally applied field". This recitation does not provide a clear description of the limitation of this claim for one having ordinary skill in the art to employ. Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At line 10 of claim 13, the claim recites "the temperature". It is unclear whether or not this recitation refers to "the temperature value" as in the language of the previous claims, or if a different temperature is being defined. The metes and bounds of the term "the temperature" is unclear considering the Applicant does not reveal a basis for which the term can be assessed. The term "the temperature" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-2, 4-5, and 9-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Fleischman et al. (U.S. Patent Number US 6,241,724 B1)

In regard to claims 1-2, 4-5, and 9-12, Fleischman et al. disclose a method for measuring temperature at a site within a patient during a medical procedure. The method comprises

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providing a medical device having at least two electrode segments and an orientation sensing mechanism (136), which provide for the assessment of electrode positioning at the site (col.2, lines 9-36). The medical device of the Fleischman et al. patent is placed within the patient and the orientation sensing mechanism (136) is positioned at the site. The device further includes temperature-sensing devices, which provide a temperature measurement signal of the environment to the orientation sensing mechanism (136). The medical device is further used to measure the voltage at the tip (140) of the orientation sensing mechanism (136). An impedance measurement is determined based on the temperature measurement signal and the voltage. An algorithm performed by the control system (200) of the Fleischman et al. device is also capable of determining the temperature value based on the resistance value (col. 6, lines 8-52). The control system has signal processing capabilities, which are employed to measure the resistance value and the temperature value at the site. The Fleischman et al. patent further includes using a signal processor for measuring the voltage at the orientation sensing mechanism (col. 12, lines 1-16). The device of the Fleischman et al. patent includes a module (23), which is an external source for delivery of RF energy applied at the site within the patient (col. 4, lines 65-67; col. 5; col. 6, lines 1-8). Fleischman et al. disclose performing an ablation procedure at the site with the medical device (col. 2, lines 9-17).

In regard to claims 13-15, Fleischman et al. disclose a method for adjusting for temperature sensitivity of a medical device having an orientation sensing mechanism (136). The method disclosed by Fleischman et al. comprises the steps of providing a medical device having an orientation sensing mechanism (136). The medical device is used to measure voltage at the tip (140) of the orientation sensing mechanism (136) and is capable of determining a resistance

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value from the measured voltage (col. 12, lines 1-16). Fleischman et al. further describe the medical device being capable of determining a temperature value and temperature sensitivity at the orientation sensing mechanism based on the resistance value (col. 5, lines 47-67; col. 6 lines 1-67; col. 7, lines 1-5). Based on the temperature information gathered, the control system of the medical device modifies the location information (col. 10, lines 27-37). Additionally, the method according to Fleischman comprises adjusting position and orientation coordinates from the orientation sensing mechanism based on the sensitivity (col.11, lines3-67; col. 12).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al. (U.S. Patent Number 6,241,724) in view of Goldin et al. (U.S. Patent Number 6,569,160).

In regard to claims 6-8, Fleischman et al. disclose a method for measuring temperature at a site within a patient during a medical procedure. The method comprises providing a medical device having at least two electrode segments and an orientation sensing mechanism (136), which provide for the assessment of electrode positioning at the site (col.2, lines 9-36). The medical device of the Fleischman et al. patent is placed within the patient and the orientation sensing mechanism (136) is positioned at the site. The device further includes temperature-sensing devices, which provide a temperature measurement signal of the environment to the orientation

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sensing mechanism (136). The medical device is further used to measure the voltage at the tip (140) of the orientation sensing mechanism (136). An impedance measurement is determined based on the temperature measurement signal and the voltage. An algorithm performed by the control system (200) of the Fleischman et al. device is also capable of determining the temperature value based on the resistance value (col. 6, lines 8-52). Fleischman et al. further describe the medical device being capable of determining a temperature value and temperature sensitivity at the orientation sensing mechanism based on the resistance value (col. 5, lines 47-67; col. 6 lines 1-67; col. 7, lines 1-5). The device of the Fleischman et al. patent includes a module (23), which is an external source for delivery of RF energy applied at the site within the patient (col. 4, lines 65-67; col. 5; col. 6, lines 1-8). Fleischman et al. disclose performing an ablation procedure at the site with the medical device (col. 2, lines 9-17). Fleischman et al. does not disclose the use of an AC generator signal. Goldin et al. disclose a system and method for detecting electrode tissue-contact, which comprises a medical catheter device having a location sensor. The medical device of the Goldin et al. patent is used to perform ablation procedures. The device includes a signal generator, which delivers an AC signal to the distal tip of the device. The generator signal of the Goldin device is capable of operating at 3KHz with the temperature measurement signal at 4Hkz. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to include an AC generator, similar to that disclosed by Goldin et al., to deliver an AC signal to a medical device similar to Fleischman's ablation apparatus, as a way to provide a means for decreasing the sensitivity of the medical device to external noise.

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9. Claims 3 and 16-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fleischman et al. (U.S. Patent Number 6,241,724) in view of Douglas et al. (U.S. Patent Number 5,638,418).

In regard to claims 3 and 16-21, Fleischman et al. disclose a method for measuring temperature at a site within a patient during a medical procedure. The method comprises providing a medical device having at least two electrode segments and an orientation sensing mechanism (136), which provide for the assessment of electrode positioning at the site (col.2, lines 9-36). The medical device of the Fleischman et al. patent is placed within the patient and the orientation sensing mechanism (136) is positioned at the site. The device further includes temperature-sensing devices, which provide a temperature measurement signal of the environment to the orientation sensing mechanism (136). The medical device is further used to measure the voltage at the tip (140) of the orientation sensing mechanism (136). An impedance measurement is determined based on the temperature measurement signal and the voltage. An algorithm performed by the control system (200) of the Fleischman et al. device is also capable of determining the temperature value based on the resistance value (col. 6, lines 8-52). The control system has signal processing capabilities, which are employed to measure the resistance value and the temperature value at the site. A profile of resistance and sensitivity versus temperature is developed from the collected information (col. 6, lines 4-67). Fleischman et al. disclose performing an ablation procedure at the site based on the resistance and sensitivity profile information (col. 2, lines 9-17). Fleischman et al. does not disclose providing a resistance drift factor to the resistance value or sensitivity drift factor to the temperature value when executing the algorithm. Douglass et al. disclose a system and method that is used to detect temperature.

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The method includes including an error term to simulate possible drift of resistance values. The system of the Douglass et al. patent uses the resistance drift coefficient during its processing step, which is stored by a memory device of the system. Douglass et al. further disclose a temperature coefficient introduced to adjust the temperature measurement according to the temperature sensitivity of the device in operation. It would have been obvious to one having ordinary skill in the art at the time the Applicants' invention was made to apply correction factors, similar to those disclosed by Douglass et al., to an algorithm used to measure temperature similar to the one used by Fleischman et al. in order to improve the accuracy of the calculated measurement and reduce sources of variability.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fangemonique Smith whose telephone number is 571-272-8160. The examiner can normally be reached on Mon - Fri 7am - 3:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CHARLES MARMOR
PRIMARY EXAMINER